



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Melody Banks

From: Tim Ciarlo, MS, Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Acting Senior Entomologist

Date: October 24, 2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 431215

Decision no.: 512087

Submission no: 978408

Action code: R260X3

Product Name: TC 303

EPA Reg. No or File Symbol: 499-540

Formulation Type: Aerosol Spray

Ingredients statement from the label with PC codes included:

Prallethrin	0.05%	PC: 128722
Dinotefuran	0.25%	PC: 044312
Pyriproxyfen	0.1%	PC: 129032

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): Use at the rate of **20 ounces [one can] for up to 2625 ft² (10 ounces [half can] for up to 1300 ft²)**, applying in a sweeping motion at a speed of **1 ft per second**.

Use Patterns: Aerosol spray for use against various pests, including application to harborages such as carpets, upholstered areas, pet beds, head boards, wall coverings, and box springs. Hold can 36 inches away from surface being treated.

I. Action Requested: The registrant has applied to expand the use patterns to include application to mattresses for residual control of bed bugs. The risk manager has requested review of one MRID submitted to support residual claims against bed bugs.

II. Background: This product already includes efficacy claims against fleas, flea eggs, bed bugs, and ticks. The currently accepted label does not include Directions for Use on mattresses for bed bug control.

III. MRID Summary (primary review is attached):

49784201. Evaluation of BAS 416 00 I against adult bed bugs (*Cimex lectularius*) on mattress ticking and ceramic tile.

(1) non-GLP

(2) **Methods:** This study intended to evaluate the residual efficacy of the subject product against bed bugs when applied to a porous surface (mattress ticking) and a non-porous surface (glazed ceramic tile). Squares of both surfaces, each measuring 6 x 6 inches, were sprayed from a height of 12 inches with 2 rates of BAS 416 00 I, which match the active ingredient profile of the subject product. The application rates tested were 6 inches/second and 12 inches/second. Only the 12 inches/second rate corresponds to the labeled rate, so only this rate will be considered in this review. Treated surfaces were then aged for 1, 3, 8, 15, 23, or 30 days. Thirty adult/late instar bed bugs (*Cimex lectularius*) were then exposed to treated surfaces such that 10 were corralled in each of three plastic rings 6 cm in diameter. One mattress ticking replicate and one ceramic tile replicate at each of the 2 rates were used at each aging interval. Thus, 30 individual bed bugs were included in each replicate. Untreated controls were included in this study, but no details on the controls were provided. No details on bed bug rearing or strain (susceptible vs. field-collected) were provided.

Bed bugs were allowed to crawl on the treated/untreated surfaces for 6 hours, at which point they were transferred to clean petri dishes with filter paper lining the bottom of each. Mortality observations were made 1, 2, and 5 days after bed bug exposure (although data were collected 3 days after exposure instead of 5 in the replicates aged 15 days). Raw data were provided.

(3) **Results:** Bed bug mortality data are summarized in the table below:

Table 1. Efficacy of BAS 416 00 I against adult bed bugs (*Cimex lectularius*) on mattress ticking and ceramic tile; BASF Corp., RTP, APR/IA, N-CAT, 2015

Surface	Treatment ¹	Rate	Mean % mortality with panels aged: ²								
			1 dat		3 dat			8 dat			
			1 d	2 d	1 d	2 d	5 d	1 d	2 d	5 d	
Mattress ticking	BAS 416 00 I	1x	16.7	90.0	93.3	93.3	100.0	93.3	93.3	96.7	
		2x	40.0	96.7	66.7	93.3	100.0	97.0	100.0	100.0	
	Untreated		10.0	20.0	10.0	10.0	13.3	3.3	13.3	30.0	
Glazed ceramic tile	BAS 416 00 I	1x	24.1	93.0	66.7	90.0	100.0	96.7	100.0		
		2x	40.0	76.7	70.0	90.0	100.0	96.7	100.0		
	Untreated		8.9	25.0	3.3	6.7	30.0	16.7	26.7		
Surface	Treatment ¹	Rate	Mean % mortality with panels aged: ²								
			15 dat			23 dat			30 dat		
			1 d	2 d	3 d	1 d	2 d	5 d	1 d	2 d	5 d
Mattress ticking	BAS 416 00 I	1x	90.9	100.0		60.0	80.0	93.3	43.3	83.3	96.7
		2x	96.7	100.0		41.1	71.5	96.7	44.1	79.3	82.2
	Untreated		10.0	16.1		0.0	3.3	20.0	6.7	16.7	30.0
Glazed ceramic tile	BAS 416 00 I	1x	83.3	96.7	96.7	75.2	100.0		61.8	83.9	97.0
		2x	83.3	100.0	100.0	79.6	83.0	96.7	73.3	86.7	96.7
	Untreated		3.3	6.7	6.7	10.0	10.0	20.0	6.7	10.0	20.0

Testing initiated 10 March 2015.

¹ BAS 416 00 I: 0.25% dinotefuran, 0.1% pyriproxyfen, 0.05% prallethrin.

² Means based on 30 insects (10 bed bugs per replicate, 3 replicates per treatment).

Mortality: no movement when probed.

Mortality only exceeded or met 90% in trials with acceptable control mortality (<10%) in the ceramic tile replicates treated at the 12 inches/second rate and aged 3 and 15 days. In both cases, $\geq 90\%$ mortality was first observed 2 days after bed bug exposure to the treated surface. In the mattress ticking replicate treated at the 12 inches/second rate and aged 8 days, mortality was reported as 93% 1 and 2 days after bed bug exposure. However, control mortality rose from 3% 1 day after exposure to 13% 2 days after exposure.

(4) **Conclusion:** This study is **unacceptable** and does not support any residual efficacy claims against bed bugs on any surface type.

IV. EXECUTIVE DATA SUMMARY:

(A) This study is deficient in the following ways:

- Bed bugs should only be exposed to a treated surface for a maximum of 4 hours, and then transferred to clean containers for mortality observations. In this study, bed bugs were exposed to treated surfaces for 6 hours and then transferred to clean containers.
- Replication was inadequate. Five replicates of 10 individuals per replicate should be used, at a minimum. This means that at least 5 surfaces of each type (porous and non-porous) at each aging interval should be used – not one per aging interval as was the case in this study.
- Containers used to apply test material should be weighed before and after application so that the actual application can be reported on a unit of mass per unit of area basis. This should correspond to the lowest labeled rate.
- Mortality in the treated replicates should be $\geq 90\%$ by 96 hours after bed bug exposure to the treated surface.
- Control mortality should not reach 10%.
- The strain of the test organisms was not reported. A field-collected bed bug strain should be used in efficacy trials.

V. LABEL RECOMMENDATIONS:

(1) The following changes in the Directions for Use are suggested:

All mention of residual control against bed bugs should be removed.

(2) The following marketing claims are acceptable:

None

(3) The following marketing claims are unacceptable:

...offers residual control of bed bugs.

(4) The following MRIDs should be removed from the data matrix, as they are classified as “unacceptable” to support the product:

49784201

(5) Note to reviewer/PM:

Only MRID 49784201 was reviewed here. Because this MRID was rated as unacceptable, no additional efficacy claims against bed bugs are appropriate for this product. The currently accepted product label does include non-residual “kills” claims against bed bugs and other pests of public health concern, which may be supported by one or more MRIDs currently listed on the data matrix. This review does not necessarily mean that the subject product should not be applied to mattresses – only that it is inappropriate to claim that it provides any residual control against bed bugs if applied to mattresses.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 497842-01. Evaluation of BAS 416 00 I against Adult Bed Bugs (*Cimex lectularius*) on Mattress Ticking and Ceramic Tile. Gordon, F.C. 2015.

OCSPP Product Performance Guideline: 810.3600, 40 CFR 158.400

Product Name: TC-303 Pressurized Flea IGR and Adulticide

EPA Reg. No. or File Symbol: 499-540

Decision number: 512087

DP number: 431215

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-304

Primary Reviewer:
Chris Peterson, Ph.D.

Signature: Chris Peterson ^{AE}
Date: 06/08/2016

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess ^{AE}
Date: 06/08/2016

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross ^{AE}
Date: 06/08/2016

Quality Assurance:
Angela M. Edmonds, B.S.

Signature: Angela M. Edmonds
Date: 06/08/2016

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

**EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY) -
Registration**

Primary Reviewer's Name/Title: Chris Peterson, Toxicologist

STUDY TYPE:	PRODUCT PERFORMANCE: OCSPP 810.3600, 40 CFR 158.400
MRID:	497842-01. Evaluation of BAS 416 00 I against Adult Bed Bugs (<i>Cimex lectularius</i>) on Mattress Ticking and Ceramic Tile. Gordon, F.C. 2015.
DP BARCODE:	431215
DECISION NO:	512087
SUBMISSION NO:	978408
SPONSOR:	Clark Klein, Sponsor
TESTING FACILITY:	BASF APR/IA Non-Crop Advanced Testing Laboratory, RTP, NC
STUDY DIRECTOR or INVESTIGATOR:	Ken Brown, Study Director
SUBMITTER:	Christine Keating, Submitter
STUDY COMPLETED:	16/11/2015
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	This study was <u>NOT</u> conducted in compliance with Good Laboratory Practice Standards as described by EPA (40 CFR Parts 160 and 792), and was never intended for that purpose.
TEST MATERIAL:	PRODUCT NAME: TC-303 Pressurized Flea IGR and Adulticide EPA REGISTRATION NUMBER OR FILE SYMBOL: 499-540 ACTIVE INGREDIENT NAME: Dinotefuran + Pyriproxyfen + Prallethrin CHEMICAL NAME: Dinotefuran: N-Methyl-N-[(Tetrahydro-3-Furanyl)Methyl]Guanidine A.I. %: Dinotefuran 0.25% + Pyriproxyfen 0.10% + Prallethrin 0.05% PC CODE: PRIA

CAS NO.: Not provided

FORMULATION TYPE: Aerosol

PRODUCT APPLICATION RATE(S): 20 oz/2625 square feet (567 g/243.9 square meters)

ACTIVE INGREDIENT APPLICATION RATE(S): 1.48 g/2625 square feet Dinotefuran + 0.59 g/2625 square feet Pyriproxyfen + 0.296 g/2625 square feet

Efficacy Study Data Evaluation Record

Title: Evaluation of BAS 416 00 I against Adult Bed Bugs (*Cimex lectularius*) on Mattress Ticking and Ceramic Tile.

Purpose/Objective:

To evaluate the potential efficacy of BAS 416 00 I (pressurized product) against adult / late instar bed bugs (*Cimex lectularius*) after various aging intervals following application to mattress ticking and glazed ceramic tile.

Materials and Methods

Test Material(s):

BAS 416 00 I: Dinotefuran 0.25%, Pyriproxyfen 0.1%, Prallethrin 0.05%

These concentrations correspond with those on the label.

Product was applied to mattress ticking or ceramic tiles at application rates of 12 inches/second and 6 inches/second. The amount of product applied was not reported, therefore a.i. rates could not be calculated.

Test Location: Research Triangle Park, North Carolina

Positive Control/Reference Standard, if used: Not used

Species Tested:

- Common name and scientific name of each species. Bed bug, *Cimex lectularius*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Adult and late instars
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Not reported
- If female adults are used - are they gravid? Not reported
- Describe rearing techniques. Not described

Experiment description:

- List the treatments including the untreated control.

BAS 416 00 I: Dinotefuran 0.25%, Pyriproxyfen 0.1%, Prallethrin 0.05%

These concentrations correspond with those on the label.

Product was applied to mattress ticking or ceramic tiles at application rates of 12 inches/second and 6 inches per second. The amount of product applied was not reported, therefore a.i. rates could not be calculated.

Untreated control replicates are reported but not described.

- Include a description of:
 - Test arenas and/or apparatus (include site description and location):
Mattress ticking (JoAnn Fabrics) was cut into 6 x 6 inch squares and glued to plywood panels for treatment. Both ticking and ceramic tiles were sprayed in a fume hood and allowed to dry. Prior to attachment with glue to dried panels, the inner surface of plastic rings (6 cm x 2 cm) was coated with Fluon to prevent insect escape and ensure contact with the treated surface. Approximately 10 insects were placed into each arena (3 rings per substrate). After 6 hours (h) exposure, the insects were removed from the treatment and held in clean, plastic Petri dishes containing filter paper for insect traction. No food or water was provided during the study. Bed bugs were exposed to treatments aged for 1, 3, 8, 15, 23, and 30 days (d) after the treatment application. Mortality data were
 - Method(s) of application: Surface
 - Number of replicates per treatment: 1
 - Number of individuals per replicate: 30 insects in 3 groups of 10 per substrate
 - Length of exposure to treatment (time in seconds, minutes or hours): 6 hr
 - Were tested specimens transferred to clean containers? Yes
 - Experimental conditions (state relative humidity, temperature, and photoperiod):
Note: For exposures aged 1, 3, and 8 d, bed bugs were held at ambient laboratory conditions. For exposures aged 15, 23, and 30 d, bed bugs were held in a darkened incubator at 27°C and 60% RH in an attempt to improve control survival.
 - The type of harborage if used in the experiment: See test apparatus description above
 - The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move):
or water was provided during the study. Bed bugs were exposed to treatments aged for 1, 3, 8, 15, 23, and 30 days (d) after the treatment application. Mortality data were collected (no movement when probed at ≥1 day post exposure). Knockdown (Kd, incapacitation ≤ 4h) data were noted as necessary.
 - Report if morbidity and mortality were recorded separately: Not recorded separately
 - Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

Table 1. Efficacy of BAS 416 00 I against adult bed bugs (*Cimex lectularius*) on mattress ticking and ceramic tile; BASF Corp., RTP, APR/IA, N-CAT, 2015

Surface	Treatment ¹	Rate	Mean % mortality with panels aged: ²								
			1 dat		3 dat			8 dat			
			1 d	2 d	1 d	2 d	5 d	1 d	2 d	5 d	
Mattress ticking	BAS 416 00 I	1x	16.7	90.0	93.3	93.3	100.0	93.3	93.3	96.7	
		2x	40.0	96.7	66.7	93.3	100.0	97.0	100.0	100.0	
	Untreated		10.0	20.0	10.0	10.0	13.3	3.3	13.3	30.0	
Glazed ceramic tile	BAS 416 00 I	1x	24.1	93.0	66.7	90.0	100.0	96.7	100.0		
		2x	40.0	76.7	70.0	90.0	100.0	96.7	100.0		
	Untreated		8.9	25.0	3.3	6.7	30.0	16.7	26.7		

Surface	Treatment ¹	Rate	Mean % mortality with panels aged: ²								
			15 dat			23 dat			30 dat		
			1 d	2 d	3 d	1 d	2 d	5 d	1 d	2 d	5 d
Mattress ticking	BAS 416 00 I	1x	90.9	100.0		60.0	80.0	93.3	43.3	83.3	96.7
		2x	96.7	100.0		41.1	71.5	96.7	44.1	79.3	82.2
	Untreated		10.0	16.1		0.0	3.3	20.0	6.7	16.7	30.0
Glazed ceramic tile	BAS 416 00 I	1x	83.3	96.7	96.7	75.2	100.0		61.8	83.9	97.0
		2x	83.3	100.0	100.0	79.6	83.0	96.7	73.3	86.7	96.7
	Untreated		3.3	6.7	6.7	10.0	10.0	20.0	6.7	10.0	20.0

Testing initiated 10 March 2015.

¹ BAS 416 00 I: 0.25% dinotefuran, 0.1% pyriproxyfen, 0.05% prallethrin.

² Means based on 30 insects (10 bed bugs per replicate, 3 replicates per treatment).

Mortality: no movement when probed.

- Deviations or amendments from the protocol. None reported
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
 - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed.

			≥90% Mortality Observed?																
			1 DAT		3 DAT			8 DAT			15 DAT			23 DAT			30 DAT		
			1 d	2d	1 d	2 d	5 d	1 d	2 d	5 d	1 d	2 d	3 d	1 d	2 d	5 d	1 d	2 d	5 d
Mattress Ticking	BAS	1x	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	No	No	Yes	No	No	Yes
		2x	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	No	No	Yes	No	No	No
Ceramic Tile	BAS	1x	No	Yes	No	Yes	Yes	Yes	Yes	-	No	Yes	Yes	No	Yes	-	No	No	Yes
		2x	No	No	No	Yes	Yes	Yes	Yes	-	No	Yes	Yes	No	No	Yes	No	No	Yes

- Tested a.i. application rate: Not determinable
- Surface tested, for residual studies (e.g. ceramic tile, wood panel): Ceramic tile, mattress ticking
- Formulation type (e.g. aerosol, granular): Aerosol
- Application type (e.g. direct, surface, area): Surface
- Timepoints at which corresponding control mortality is greater than 10%:

	≥10% Control Mortality Observed?																
	1 DAT		3 DAT			8 DAT			15 DAT			23 DAT			30 DAT		
	1 d	2d	1 d	2 d	5 d	1 d	2 d	5 d	1 d	2 d	3 d	1 d	2 d	5 d	1 d	2 d	5 d
Mattress Ticking	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	-	No	No	Yes	No	Yes	Yes
Ceramic Tile	No	Yes	No	No	Yes	Yes	Yes	-	No	No	No	Yes	Yes	Yes	No	Yes	Yes

Conclusions

- Application of BAS 416 00 I at 12 inches/second (1x) and 6 inches/second (2x) caused ≥90% mortality to bed bugs at the days after 6 hr exposure indicated on the indicated surfaces at the indicated days after treatment in the following table:

			≥90% Mortality Observed?																
			1 DAT		3 DAT			8 DAT			15 DAT			23 DAT			30 DAT		
			1 d	2d	1 d	2 d	5 d	1 d	2 d	5 d	1 d	2 d	3 d	1 d	2 d	5 d	1 d	2 d	5 d
Mattress Ticking	BAS	1x	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	No	No	Yes	No	No	Yes
		2x	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	No	No	Yes	No	No	No
Ceramic Tile	BAS	1x	No	Yes	No	Yes	Yes	Yes	Yes	-	No	Yes	Yes	No	Yes	-	No	No	Yes
		2x	No	No	No	Yes	Yes	Yes	Yes	Yes	-	No	Yes	Yes	No	No	Yes	No	No

- The concentrations tested here correspond with those on the label.
- The amount of product applied was not reported, therefore a.i. rates could not be calculated.
- The study presented here represents a single replication with three sampling units rather than three replications as only on application of the product at each dose was conducted.
- Control mortality surpassed 10% in 21 of 32 cases (66% of all control observations.)